



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE CENTER 1600/

In re Application of: Serial No.: Filing Date: Docket Number: Title: CEFALI, EUGENIO 08/962,027 31 October 1997 50454-56103USCIP1

INTERMEDIATE RELEASE NICOTINIC ACID COMPOSITIONS FOR TREATING HYPERLIPIDEMIA HAVING UNIQUE CMAX, TMAX AND AUC BIOPHARMACEUTICAL CHARACTERISTICS

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

Applicants and their attorney are aware of the following publications and information, listed on the attached PTO Form 1449, and in accordance with 37 CFR §1.97(c) hereby submit these publications for the Examiner's consideration. This Statement is being filed after the first Official Action under 37 CFR §1.97(c)(2). Please charge our deposit account number 50-2543 the amount of \$180.00 as specified in 37 CFR § 1.17(p). A full copy of each cited publication is enclosed.

This statement is not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any publication herein be construed *per se* as a representation that such publication is prior art. Moreover, the Applicant understands the Examiner will make an independent evaluation of the cited publications. No additional costs are believed to be due in connection with the filing of this disclosure. However, please charge any necessary fees to our Deposit Account No. 12-0448. For this purpose we enclose a duplicate copy of this document.

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Respectfully submitted

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CERTIFICATION UNDER 37 C.F.R., §1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450on the Late indicated below.

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Substitute for form 1449B/PTO

Complete if Known **INFORMATION DISCLOSURE Filing Date** 10/31/1997 STATEMENT BY APPLICANT First Named Inventor Cefali Group Art Unit (use as many sheets as necessary) **Examiner Name** of Attorney Docket Number Sheet 1 50454-56103USCIP1

Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T2
	1	Dialog File 226: Trademarkscan(r)-US FED: Accession number 73/838497	
	2	McCarthy on Patents, Sec. 19.110	
	3	199 U.S.P.Q. 824 (Endo Laboratories, Inc. v. Fredericks, 08/18/1978)	
	4	KEENAN, et al., A Clinical Trial of Oat Bran and Niacin in the Treatment of Hyperlipidemia", Jour. Fam. Prac., 34:3, 313-317 (1992)	
	5	KNOPP, et al., "Contrasting Effects of Unmodified and Time-Release forms of Niacin on Lipoproteins in Hyperlipidemic Subjects: Clues to Mechanism of Action of Niacin", Metabolism, 34:7, 642-650 (1985)	
<u> </u>	6	Letter to Applicant from U.S. Department of Health and Human Services dated 07/28/1997	
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